

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION

Master Docket No. 1:17-MD-02804-  
DAP  
MDL No. 2804

This Document Relates to:  
  
ALL ACTIONS

Hon. Dan A. Polster

**CASE MANAGEMENT ORDER NO. \_\_:  
PROTECTIVE ORDER**

**I. Scope of Order**

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order (“Protective Order” or “Order”). Unless otherwise noted, this Order is also subject to the Local Rules of this District and the Federal Rules of Civil Procedure on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, captioned as *In re: National Prescription Opiate Litigation* (MDL No. 2804), Case No. 1:17-CV-2804, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there (“the Litigation”). All materials produced or adduced in the course of discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony,

discovery response or otherwise, by any Party to this Litigation (the “Producing Party”) to any other party or parties (the “Receiving Party”). This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

## **II. Definitions**

7. Party. “Party” means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. “Discovery Material” means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) (“Computerized Material”) is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation.

9. Competitor. Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 38 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant, except as provided in Paragraphs 33 or 34.

10. Confidential Information. “Confidential Information” is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes,

reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner's records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Confidential."

11. Highly Confidential Information. "Highly Confidential Information" is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Highly Confidential."

12. Manufacturer Defendant: Manufacturer Defendant means any Defendant in this litigation that manufactures any Opioid Product for sale or distribution in the United States.

13. Distributor Defendant: Distributor Defendant means any Defendant in this litigation that distributes any Opioid Product in the United States other than a product they manufacture or

license for manufacture.

14. Retail Defendant. Retail Defendant means any Defendant in this litigation that sells or distributes any Opioid Product directly to consumers in the United States.

15. Receiving Party. “Receiving Party” means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.

16. Producing Party. “Producing Party” means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.

17. Protected Material. “Protected Material” means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as “Confidential” or “Highly Confidential” in accordance with this Protective Order.

18. Outside Counsel. “Outside Counsel” means any law firm or attorney who represents any Party for purposes of this litigation.

19. In-House Counsel. “In-House Counsel” means attorney employees of any Party.

20. Counsel. “Counsel,” without another qualifier, means Outside Counsel and In-House Counsel.

21. Independent Expert. “Independent Expert” means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

22. This Litigation. “This Litigation” means all actions in MDL No. 2804, *In re: National Prescription Opiate Litigation* or hereafter subject to transfer to MDL No. 2804.

### **III. Designation and Redaction of Confidential Information**

23. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

24. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party’s receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as “HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW.” Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be

deemed not to contain Confidential Information or Highly Confidential Information and the “HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW” legend shall be removed.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34, below, along with the witness and the witness’s counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes qualifies as the designating Party’s Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production or to permit the “Confidential Information” or “Highly Confidential Information” designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the

Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Confidential Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact:

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.

30. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at



issue in this litigation), the Producing Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product(s) would render the information pertaining to Producing Party's opioid product meaningless or would remove the context of the information about Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

31. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

#### **IV. Access to Confidential and Highly Confidential Information**

32. General. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential Information to any third person or entity except as set forth in Paragraphs 33 and 34.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.1) and

its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

- i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.
- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order; or
- l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall

disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order.

- m. Witnesses during the course of deposition on such terms and conditions as may be provided for by further Order of the Court.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification

contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;

- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;;
- c. Individual Parties that have produced the designated information;
- d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- g. Any individual(s) who authored, prepared or previously reviewed or received the information;
- h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the

Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.

- i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order; or
- j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments

available to such claimant.

- k. Witnesses during the course of deposition on such terms and conditions as may be provided for by further Order of the Court.

35. With respect to documents produced to Plaintiffs, documents designated as “HIGHLY CONFIDENTIAL” will be treated in the same manner as documents designated “CONFIDENTIAL,” except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Producing Party, except as otherwise provided in this Order or any other Order in this Litigation.

36. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

#### **V. Confidentiality Acknowledgment**

37. Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no

attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

#### **VI. Litigation Experts and Consultants.**

38. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 37 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Producing Party in writing, which may include by e-mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying



Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.

39. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Producing Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Section 9(o) of Case Management Order One, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

## **VII. Protection and Use of Confidential and Highly Confidential Information**

40. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential

Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

41. Nothing herein shall restrict a person qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

42. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 46. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

43. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such

information, provided that in rendering such advice, Counsel shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

44. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing

45. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

47. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

48. Unless otherwise agreed or ordered, this Protective Order shall remain in force

after dismissal or entry of final judgment not subject to further appeal of this Litigation.

49. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;<sup>1</sup> or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.

50. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

#### **VIII. Changes in Designation of Information**

51. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in

---

<sup>1</sup> The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” or withdraw a “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL”, the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party’s good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

52. A Receiving Party does not waive its right to challenge a confidentiality

designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Section 9(o) of Case Management Order One. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the event that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media, images, and associated production information as provided above.

#### **IX. Inadvertent Production of Documents**

53. Non-Waiver of Privilege. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of

further showing under Federal Rule of Evidence 402(b) and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the “Disclosing Party”). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).

54. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

55. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party’s system:

i. Locate each recalled document in the document review/production database and delete the record from the database;

ii. If there is a native file link to the recalled document, remove the native file from the network path;

iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents.

Remove the line(s) corresponding to the document image(s) from the image load file;

iv. Apply the same process to any additional copies of the document or database, where possible;

v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as described herein;

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this



Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted (“Clawed-Back Information”), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party’s privilege log with respect to such Clawed-Back Information, a receiving party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party’s privilege or work-product claim with respect to such Clawed-Back Information. The parties may stipulate to extend the time periods set forth in this paragraph.

58. If, for any reason, the Disclosing Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order One. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

59. Nothing contained herein is intended to or shall serve to limit a party’s right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.

61. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

**X. Filing and Use at Trial of Protected Material**

62. Only Confidential or Highly Confidential portions of relevant documents are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any confidential information. If, however, the confidential information must be intertwined within the text of the document, a party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

63. Absent a Court-granted exception based upon extraordinary circumstances, any and all filings made under seal shall be submitted electronically and shall be linked to this Stipulated Protective Order or other relevant authorizing order. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.

64. If the Court has granted an exception to electronic filing, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the party on whose behalf it is submitted, and the name of the attorney

who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.

65. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information at the hearing. The use of any Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

**XI. Information or Highly Confidential Information Requested by Third Party;  
Procedure Following Request.**

66. If any person receiving Discovery Material covered by this Protective Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order ("Request"), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.

67. The Receiver also must immediately inform the party who made the Request ("Requesting Party") in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.

68. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party

shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

69. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the “Public Disclosure Laws”), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclosure; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any

arguments that a Party may make as to why Discovery Material is exempt from disclosure.

## **XII. HIPAA-Protected Information**

70. General. Discovery in this Litigation may involve production of “Protected Health Information” as that term is defined and set forth in 45 C.F.R. § 160.103, for which special protection from public disclosure and from any purpose other than prosecuting this Action is warranted

71. “Protected Health Information” shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 (“Covered Entities”) or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 (“Business Associate”) in the course of the Litigation, as well as information covered by the privacy laws of any individual states, as applicable.

72. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material “Confidential Protected Health Information” in accordance with the provisions of this Protective Order.

73. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as “Confidential Protected Health Information” shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as “Confidential Protected Health Information” made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as “Confidential Protected Health Information” shall be made in the following manner: (a) or documents, by placing

the notation “Confidential Protected Health Information” or similar legend on each page of such document; (b) for tangible things, by placing the notation “Confidential Protected Health Information” on the object or container thereof or if impracticable, as otherwise agreed by the parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation “Confidential Protected Health Information” both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being “Confidential Protected Health Information” at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

74. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Action to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings.

75. The Parties shall not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may, inter alia, disclose Protected Health Information to (a) counsel for the Parties and employees of counsel who have

responsibility for the Litigation; (b) the Court and its personnel; (c) Court reporters; (d) experts and consultants; and (e) other entities or persons involved in the Litigation.

76. Within sixty days after dismissal or entry of final judgment not subject to further appeal, the Parties, their counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order shall destroy or return to the Covered Entity or Business Associate such Protected Health Information.

77. Nothing in this Order authorizes the parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

**XIII. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.**

78. In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party's production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief,

the Party shall promptly produce the information in question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

#### **XIV. Miscellaneous Provisions**

79. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

80. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

81. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

82. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

83. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.



84. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

85. This Order is entered based on the representations and agreements of the parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any documents or information designated as Confidential or Highly Confidential by counsel or the parties is subject to protection under Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

**IT IS SO ORDERED:**

Dated: \_\_\_\_\_,

\_\_\_\_\_  
Honorable Dan Aaron Polster  
United States District Judge

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION

Master Docket No. 1:17-MD-02804-DAP  
MDL No. 2804

This Document Relates to:

Hon. Dan A. Polster

ALL ACTIONS

**EXHIBIT A TO CASE MANAGEMENT ORDER NO. \_\_\_\_\_**

**ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. \_\_) that was issued by the United States District Court for the Northern District of Ohio on \_\_\_\_\_, 2018 in *In re: National Prescription Opiate Litigation* (the “Protective Order”).

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Date:\_\_\_\_\_

City and State where sworn and signed:\_\_\_\_\_

Printed Name:\_\_\_\_\_

Signature:\_\_\_\_\_